K062712

510K SUMMARY

Submitted By:	ERBE USA, Inc. 2225 Northwest Parkway Marietta, GA 30067 Tel: 770-955-4400 Fax: 770-955-2577
Contact Person:	John Tartal QA/RA Manager
510(k) Number:	JAN 26 2007
Date Prepared:	September 7, 2006
Common Name:	Monopolar Attachment for Water Jet Dissector
Trade/Proprietary Name:	ERBE Monopolar Attachment for Helix Hydro-Jet™
Classification Name:	Jet Lavage (21 CFR Part 880.5475) and Electrosurgical cutting and coagulation device and accessories (21 CFR 878.4400)
Product Code:	FQH and GEI
Legally Marketed Predicate Devices:	ERBE Helix Hydro-Jet™ System, 510(k) Number: K033590 ERBE ESU (ICC or VIO Models) Systems, 510(k) Numbers: K953738; K953159; K935815; K933002; K933157; K060484 ERBE Disposable Push Button Pencil, 510(k) Number: K936304

Device Description:

General Description. The ERBE Monopolar Attachment [P/N 20139-094] is used with the Helix Hydro-Jet™ and the ERBE Electrosurgical Generator (ESU) Systems (ICC or VIO Models). The Helix Hydro-Jet™ is a hydraulic pressure delivery system that uses physiological saline to cut and dissect soft tissue. The ERBE Electrosurgical Generator (ESU) Systems (ICC or VIO Models) deliver High Frequency (HF) energy through the electrode tip of the ERBE Monopolar Attachment for coagulation and cutting of tissue. The ERBE Monopolar Attachment for Helix Hydro-Jet™ is made of stainless steel with plastic insulation except at the electrode tip (which isolates the HF energy to only the tip surface). The ERBE Monopolar Attachment has a channel and ring where the Helix Hydro-Jet™ Applicator slides into the Monopolar Attachment and is held in place for the Physician. The Monopolar Attachment is provided non-sterile and is reusable. (Note: The cleaning and sterilization processes are provided in the proposed draft labeling, "Notes on Use" - ERBE Monopolar Attachment.)

Intended Use:

The Monopolar Attachment combines the use of the Helix Hydro-Jet™ Applicator with suction (Part Number 20139-074) with the use of monopolar coagulation and cutting (optional drip irrigation is also available) when used in conjunction with an ERBE ESU (ICC or VIO Models).

Note: The Electrosurgical Unit (ESU) to be used must have a Monopolar 3-pin bovie receptacle. The use of ERBE ESU ICC and VIO Models are recommended. Compatibility and settings should be demonstrated/established prior to using a different Generator in the clinical environment.

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Similarities and Differences of the Proposed Devices to the Predicate Devices Comparison/Substantial Equivalence):

Similarities

The ERBE Monopolar Attachment allows the physician to combine the use of the ERBE Helix Hydro-Jet™ for water jet dissection with the ERBE Electrosurgical Generator (ESU) Systems (ICC or VIO Models) for monopolar coagulation and cutting. The use of the ERBE Monopolar Attachment does not change the way the Physician uses the ERBE Helix Hydro-Jet™ System and Applicators or the ERBE Electrosurgical Generator (ESU) Systems (ICC or VIO Models). The ERBE Monopolar Attachment for Helix Hydro-Jet™ has the same intended use as the ERBE Helix Hydro-Jet™ System with the combined ability of the intended use of the ERBE ESU. While the energy sources are still used separately, the Monopolar Attachment combines their instrumentation parts into one handheld piece.

Differences

The ERBE Monopolar Attachment is different from the use of the ERBE Helix Hydro-Jet™ for water jet dissection with the ERBE Electrosurgical Generator (ESU) Systems (ICC or VIO Models) for Monopolar coagulation/cutting in that the predicate method was for the Physician to pick up each instrument separately, use the instrument, then pick up the next instrument. Again while the energy sources are still used separately, the Monopolar Attachment combines their instrumentation parts into one handheld piece.

All the instrument design changes have been verified or validated in design control by ERBE Elektromedizin GmbH.

Conclusion:

The ERBE Monopolar Attachment for Helix Hydro-Jet™ has the same intended use, principles of operation, and technological characteristics as the predicate devices that were previously cleared for market in a 510(k).

The ERBE Monopolar Attachment differs only in that it allows the Physician to combine the instrumentation parts of the ERBE Helix™ Hydro-Jet for water jet dissection with the ERBE Electrosurgical Generator (ESU) Systems (ICC or VIO Models) for monopolar coagulation and cutting into one handheld piece.

In conclusion, there are no issues with the ERBE Monopolar Attachment for Helix Hydro-Jet™ that would raise additional safety or efficacy issues when compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

ERBE USA, Inc.
% Mr. John Tartal
QA/RA Manager
2225 Northwest Parkway
Marietta, Georgia 30067

JAN 26 2007

Re: K062712
Trade/Device Name: ERBE Monopolar Attachment for Helix Hydro-Jet™
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: January 18, 2007
Received: January 19, 2007

Dear Mr. Tartal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: ERBE Monopolar Attachment for Helix Hydro-Jet™

Indications For Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062212